K 052468

OCT 5 - 2005

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____

1. Submitter's Identification:
Mr. Fangyi Liu
Inteo Metal Products (Zhenjiang) Co., Ltd.
West Xinggang Rd. Dagang Zhenjiang, Jiangsu, China (Mechanical & Electrical Industrial Park)
Date Summary Prepared: August 18,2005

2. Name of the Device:
Inteo Metal Products (Zhenjiang) Co., Ltd.

YK9000 Series Manual Wheelchair

3. Predicate Device Information and Substantial Equivalence:
Inteo Metal Products (Zhenjiang) Co., Ltd. YK9000 Series Manual Wheelchair is substantially equivalent in safety and effectiveness to the Invacare Corporation Tracer SX, the Tracer series of Manual Wheelchair (K935398).

4. Intended Use:

The intended use of Inteo Metal Products (Zhenjiang) Co., Ltd. YK9000 Series Manual Wheelchair is to provide mobility to persons limited to a sitting position.

5. Device Description:

Classified by FDA's Physical Medicine panel as Class I, 21 CFR 890.3850, Wheelchair (Mechanical), product code is IOR. The Inteo Metal Products (Zhenjiang) Co., Ltd. YK9000 Series Manual Wheelchair is wheelchair that provides mobility to persons limited to a sitting position. It consist a rigid, mechanical, Aluminum Alloy frame and leatherette upholstery that meets ENI 021-1: Assessment of the Ignitability of Upholstered Furniture. It has two larger rear wheels with hand rims for pushing and steering, two smaller front casters for turning and maneuverability.

6. Technological Characteristics Summary:

The standards used for Inteo Metal Products (Zhenjiang) Co., Ltd. Wheelchair production are based on the following standards:

ISO 7176-1	Wheelchair: Determination of static Stability
ISO 7176-3	Wheelchair: Determination of efficiency of brakes
ISO 7176-8	Wheelchair: Requirements and test methods *for* static, impact and *f* fatigue strengths.
ISO 7176-11	Wheelchair: Test dummies.
ISO 7176-15	Wheelchair: Requirements *for* information disclosure, documentation and labeling.
ISO 7176-16	Wheelchair: Resistance of ignition of upholstered parts - Requirements and test methods.
EN 1021-1	Furniture - Assessment of the Ignitability of Upholstered Furniture.

7. Conclusion:

Inteo Metal Products (Zhenjiang) Co., Ltd. YK9000 Series Manual Wheelchair conform fully to the standards which be mentioned in Section 6 as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 6: There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 - 2005

Intco Metal Products (Zhenjiang) Co., Ltd.
c/o John Zhao
Official Correspondent
Basic Medical Industries, Inc.
12390 East End Avenue
Chino, California 91710

Re: K052468
Trade/Device Name: YK9000 Series Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: September 13, 2005
Received: September 28, 2005

Dear Mr. Zhao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment A

510(k) NUMBER (IF KNOWN) :
DEVICE NAME: Inteo Metal Products (Zhenjiang) Co., Ltd.
INDICATIONS FOR USE: YK9000 Series Manual Wheelchair

A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use_____ (Per 21 CFR 801 Subpart D) AND/OR Over- The-Counter-Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrent of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052468